

REMARKS

Claims 33 - 42 remain pending in this application. Claim 33 - 42 has been amended to more particularly point out and distinctly claim the subject matter of the invention. In view of the above amendment and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 33- 42 stand rejected under 35 U.S.C. § 112, first paragraph, as indefinite for failing to comply with the written description requirement. In view of the above amendments to the specification, it is respectfully submitted that these claims fully comply with § 112 and that this rejection should be withdrawn.

Support for the amendments to the specification may be found in U.S. Patent No. 6,126,058 and U.S. Patent No. 5,868,760 which are incorporated by reference in the present application.

Claims 33 - 37 and 40 - 42 stand rejected under 35 U.S.C. 103(a) as unpatentable over Kreizman (U.S. Patent No. 6,214,018) in view of Mascuch (U.S. Patent No. 4,796,637) and McGuckin, Jr. (U.S. Patent No. 5,868,760). The Examiner stated, in support of the rejection, that Kreizman substantially discloses Applicant's invention, but does not teach an elongated body extending from a naturally occurring body orifice, but that McGuckin Jr. teaches an elongated flexible body that is inserted via a naturally occurring body orifice and that it would have been obvious "to have provided a flexible medical device in order to reach any portion of a body lumen into which [the] apparatus is inserted and further to insert via a naturally occurring body orifice to preclude from additional surface incision trauma to the patient as taught by McGuckin Jr."

Claim 33 recites a tissue resectioning system, comprising "a resection head

mounted at a distal end of an elongate flexible body, the resection head including a marker thereon wherein, when in an operative position, the resection head is located within a body lumen with the elongate flexible body extending through the body lumen from a naturally occurring body orifice” and “an imager which remains outside the patient’s body, the imager generating image data of a selected region within the patient’s body including a predetermined portion of tissue marked for resection” in combination with “an image processing unit analyzing the image data to define a region of tissue to be resected and to locate the marker” and “a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.”

In contrast, Kreizman shows a device for the removal of tissue from a body part including a body part holder for holding the body part immobile so that a point of reference may be defined relative to the immobilized body part. (Specification, col. 2, lines 4 - 8). Thus, this system is completely incompatible with a flexible system to operate within a body lumen where the region of tissue in question cannot be immobilized. The method of the claimed invention includes the step of “holding a body part of a patient having a region of interest therein relative to a predetermined point of reference.” (Specification, col. 2, lines 49 - 51). More specifically, “the apparatus 10 includes a body part holder 12 adapted to hold a body part 14, such as a breast, immobile and to define a predetermined point of reference.” (*Id.*, col. 3, lines 50 - 52). The imaging assembly is “adapted to obtain stereotactic images of the body part 14 held by holder 12 and the region of interest therein.” (*Id.*, col. 3, lines 58 - 60). Furthermore, the volume of tissue to be removed is defined based on the predetermined point of reference which is defined by the holder 12. (*Id.*, col. 4, lines 36 - 38). The holder 12 is described as including a movable compression paddle 44 and a movable compression plate 46 which define a predetermined point of reference about the breast 14 and which hold the breast immobile and compressed. (*Id.*, col. 5, lines 23 - 27). In the method 100, the first step is to hold a body part of a patient having a region of interest therein to establish a point of reference for the apparatus. (*Id.*, col. 6, lines 22 - 25).

Thus, it is respectfully submitted that the apparatus and method of Kreizman are

suitable only for use with body parts which can be immobilized relative to an imaging apparatus and that there is no showing or suggestion of a solution which would allow this system to be used with a resection head located within a body lumen with an elongate flexible body extending through the body lumen from a naturally occurring body orifice” in combination with “an imager which remains outside the patient’s body generating image data of a selected region within the patient’s body including a predetermined portion of tissue marked for resection and an image processing unit analyzing the image data to define a region of tissue to be resected and to locate the marker” and “a control unit controlling the resection head based on the defined region of tissue and the location of the marker to resect the region of tissue.” Specifically, Kreizman neither shows nor suggests any apparatus which would allow such a volume of tissue in an internal organ to be located and defined so that a resection device could be controlled to remove the volume of tissue.

Furthermore, there is ample legal authority for the proposition that the prior art must suggest the desirability of doing what an applicant has done. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991) and it is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991). Put another way, *it is improper to modify a prior art reference unless the prior art suggests the desirability of the specific modification.* In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

It is respectfully submitted that Kreizman is wholly incompatible with flexible

systems for resection of tissue from internal organs and that the modifications suggested by the Examiner find no motivation in Kreizman and are actually taught away from by that reference. In addition, neither of Mascuch and McGuckin either show or suggest any system for the location and identification of tissue to be resected with automatic control of a resectioning device based thereon and that these references also provide no motivation for the suggested combination.

It is respectfully submitted that none of the cited references either shows or suggests such a tissue location solution and that claim 33 is not rendered obvious by Kreizman, Mascuch and McGuckin, either taken alone or in combination.

Because claims 34 - 37 and 40 - 42 depend from and, therefore, include all of the limitations of claim 33, it is submitted that these claims are also allowable.

Claims 38 and 39 stand rejected under 35 U.S.C. § 103 as obvious over Kreizman, Mascuch and McGuckin in further view of Aida (U.S. Patent No. 5,485,839). The Exam

It is respectfully submitted that Aida also fails to cure the defects in the combination of Kreizman, Mascuch and McGuckin described above in regard to claim 33. Nor does Aida provide any motivation for the suggested combination. Therefore, it is respectfully submitted that claims 38 and 39 are also not rendered obvious by Kreizman, Mascuch, McGuckin and Aida, either taken alone or in combination.

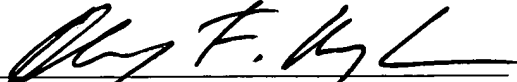
It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated:

Sept. 4, 2003

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